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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,633	04/13/2004	Markus Stoffel	1119-14	6325

23869 7590 01/05/2007

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EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	**PAPER NUMBER**
1635	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,633	STOFFEL ET AL.	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-67* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, 60, 62 and 63, drawn to an isolated DNA or RNA molecule, classified in class 536, subclass 24.5. **Upon election of this group, applicant is required to further elect a single sequence, as explained below.**

II. Claims 12-17 and 61, drawn to a modified single stranded pancreatic islet microRNA molecule, classified in class 536, subclass 24.5. **Upon election of this group, applicant is required to further elect a single sequence, as explained below.**

III. Claims 18-54, 64 and 65, drawn to an isolated single stranded anti-microRNA molecule, classified in class 536, subclass 24.5. **Upon election of this group, applicant is required to further elect a single sequence, as explained below.**

IV. Claims 55-58, drawn to a method for inhibiting microRNP activity in a cell, classified in class 435, subclass 6. **Upon election of this group, applicant is required to further elect a single sequence, as explained below.**

V. Claims 59, 66 and 67, drawn to a method for treating diabetes in a mammal in need thereof, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions of groups I-III are directed to related compounds. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. The isolated DNA or RNA molecule of group I, the modified single stranded pancreatic islet microRNA molecule of group II, and the isolated single stranded anti-microRNA molecule of group III are each structurally unique, having no common structural core. Each of the molecules function differently based on the specific structure of the molecule. To search for any one of the inventions of groups I-III would not necessarily return art against any of the other inventions. Therefore, to search more than one of the above inventions in the same application presents an undue search and examination burden.

The inventions of groups I and II are directed to products that are unrelated to the process of group IV. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the products of groups I and II are not used in the process of group IV. Group IV is specifically drawn to a method comprising introducing the product of group III into a cell, which does not involve the products of groups I or II.

To search for the inventions of groups I or II would not necessarily return art against the invention of group IV. Therefore, to search more than one of the above inventions in the same application presents an undue search and examination burden.

The inventions of groups I-III are directed to products that are unrelated to the process of group V. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the products of groups I-III are not used in the process of group V. Group V is specifically drawn to a method comprising introducing an effective amount of an anti-microRNA molecule having at least ten contiguous bases having a sequence shown in SEQ ID NO: 41, which does not involve the products of groups I-III. None of the other inventions involve consideration of an anti-microRNA molecule having at least ten contiguous bases having a sequence shown in SEQ ID NO: 41. To search for the inventions of groups I-III would not necessarily return art against the invention of group V. Therefore, to search more than one of the above inventions in the same application presents an undue search and examination burden.

Inventions of groups III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the anti-microRNA molecule of group III can be used in a materially different process, such as a screening assay. To search for one of the inventions would not necessarily return art

against the other invention. Therefore, to search more than one of the above inventions in the same application presents an undue search and examination burden.

The inventions of groups IV and V are directed to unrelated processes. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the processes of groups IV and V each comprise separate method steps that do not overlap in scope. To search for one of the inventions would not necessarily return art against the other invention. Therefore, to search more than one of the above inventions in the same application presents an undue search and examination burden.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is

earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claims 1, 2, 10-13, 18, and 22 are subject to restriction since the claims are not considered to be a proper genus/Markush. See MPEP 803.02-PRACTICE RE

MARKUSH-TYPE CLAIMS- If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush grouping the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 7169, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ 2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

The claims recite various SEQ ID NOS. The Markush/genus of sequences in claims 1, 2, 10-13, 18, and 22 is not considered to constitute proper genus, as each sequence is structurally unique. Although each of the sequences comprise nucleotides, it is the sequence of such nucleotides which provides for their activity. Because the sequences, and thus the structures that provide for function differ, and because no common structure is found from one sequence to the next, the restriction is therefore proper. Furthermore, a search of more than one of the sequences in the above claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one of the claimed

sequences. Accordingly, upon election of groups I-IV, applicants are required to elect one nucleotide sequence for search and examination.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is (571) 272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JON E. ANGELL, PH.D.
PRIMARY EXAMINER

Amy H Bowman
Examiner
Art Unit 1635

AHB